



Clinical trial results:

A Phase 2 Trial of Pembrolizumab (MK-3475) in Combination with Platinum Doublet Chemotherapy and Radiotherapy for Participants with Unresectable, Locally Advanced Stage III Non-Small Cell Lung Cancer (NSCLC) (KEYNOTE-799)

Summary

EudraCT number	2018-000714-37
Trial protocol	GB ES FR PL
Global end of trial date	19 March 2024

Results information

Result version number	v1 (current)
This version publication date	22 March 2025
First version publication date	22 March 2025

Trial information

Trial identification

Sponsor protocol code	3475-799
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03631784
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme LLC
Sponsor organisation address	126 East Lincoln Avenue, P.O. Box 2000, Rahway, NJ, United States, 07065
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme LLC, ClinicalTrialsDisclosure@msd.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme LLC, ClinicalTrialsDisclosure@msd.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	19 March 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	18 October 2021
Global end of trial reached?	Yes
Global end of trial date	19 March 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This is a trial in adult participants with unresectable, locally advanced, Stage III non-small cell lung cancer (NSCLC) treated with pembrolizumab in combination with platinum doublet chemotherapy and standard thoracic radiotherapy followed by pembrolizumab monotherapy. The primary hypothesis of the trial is that within each platinum doublet chemotherapy cohort, the percentage of participants who develop Grade 3 or higher pneumonitis is $\leq 10\%$ and estimation of objective response rate (ORR) by blinded independent central review (BICR).

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 October 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 15
Country: Number of subjects enrolled	France: 30
Country: Number of subjects enrolled	Germany: 25
Country: Number of subjects enrolled	Korea, Republic of: 23
Country: Number of subjects enrolled	New Zealand: 3
Country: Number of subjects enrolled	Poland: 21
Country: Number of subjects enrolled	Russian Federation: 31
Country: Number of subjects enrolled	Spain: 24
Country: Number of subjects enrolled	United Kingdom: 10
Country: Number of subjects enrolled	United States: 34
Worldwide total number of subjects	216
EEA total number of subjects	100

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	104
From 65 to 84 years	109
85 years and over	3

Subject disposition

Recruitment

Recruitment details:

Participants with unresectable, locally advanced, Stage III non-small cell lung cancer (NSCLC), who had received no prior anticancer therapy for their disease were recruited into two cohorts.

Pre-assignment

Screening details:

Of 216 participants enrolled/allocated in the trial, 214 received treatment.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Pembrolizumab + cCRT + Paclitaxel + Carboplatin

Arm description:

Participants received 1 cycle of carboplatin area under the curve (AUC) 6 mg/mL/min with paclitaxel 200 mg/m² and pembrolizumab 200 mg on Day 1. Approximately 3 weeks later, participants received carboplatin AUC 2 mg/mL/min with paclitaxel 45 mg/m² administered weekly for 6 weeks along with 2 cycles of pembrolizumab 200 mg administered every 3 weeks (Q3W) in conjunction with standard thoracic radiotherapy (TRT) (60 Gray [Gy] in 2 Gy fractions administered 5 days per week for 6 weeks). Participants then received 14 additional cycles of pembrolizumab 200 mg administered Q3W. 1 cycle=21 days.

Arm type	Experimental
Investigational medicinal product name	MK-3475
Investigational medicinal product code	
Other name	Pembrolizumab
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Pembrolizumab 200 mg intravenous (IV) infusion on Days 1 of each 3-week cycle for up to 17 cycles

Investigational medicinal product name	Carboplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Carboplatin AUC6 IV infusion on Day 1 of the 21-day cycle for Cycle 1

Investigational medicinal product name	Paclitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Paclitaxel 45 mg/m² IV infusion on Days 1, 8, 15 of each 3-week cycle for Cycles 2, and 3 during radiation therapy

Arm title	Pembrolizumab + cCRT + Pemetrexed + Cisplatin
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Arm description:

Participants received 3 cycles of cisplatin 75 mg/m² with pemetrexed 500 mg/m² and

pembrolizumab 200 mg on Day 1 of each cycle. Treatment was given in conjunction with standard TRT (60 Gy in 2 Gy fractions administered 5 days per week for 6 weeks) in cycles 2 and 3. Participants then received 14 additional cycles of pembrolizumab 200 mg administered Q3W. 1 cycle=21 days.

Arm type	Experimental
Investigational medicinal product name	MK-3475
Investigational medicinal product code	
Other name	Pembrolizumab
Pharmaceutical forms	Concentrate and solvent for solution for injection, Injection
Routes of administration	Intravenous use

Dosage and administration details:

Pembrolizumab 200 mg intravenous (IV) infusion on Days 1 of each 3-week cycle for up to 17 cycles

Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravascular use

Dosage and administration details:

Cisplatin 75 mg/m² IV infusion on Day 1 of each 21-day cycle for Cycles 1, 2, 3.

Investigational medicinal product name	Pemetrexed
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Pemetrexed 500 mg/m² IV infusion on Day 1 of each 21-day cycle for Cycles 1, 2, and 3.

Number of subjects in period 1	Pembrolizumab + cCRT + Paclitaxel + Carboplatin	Pembrolizumab + cCRT + Pemetrexed + Cisplatin
Started	112	104
Treated	112	102
Completed	0	0
Not completed	112	104
Consent withdrawn by subject	3	3
Sponsor's Decision	36	52
Death	71	49
Participants Ongoing	1	-
Lost to follow-up	1	-

Baseline characteristics

Reporting groups

Reporting group title	Pembrolizumab + cCRT + Paclitaxel + Carboplatin
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Reporting group description:

Participants received 1 cycle of carboplatin area under the curve (AUC) 6 mg/mL/min with paclitaxel 200 mg/m² and pembrolizumab 200 mg on Day 1. Approximately 3 weeks later, participants received carboplatin AUC 2 mg/mL/min with paclitaxel 45 mg/m² administered weekly for 6 weeks along with 2 cycles of pembrolizumab 200 mg administered every 3 weeks (Q3W) in conjunction with standard thoracic radiotherapy (TRT) (60 Gray [Gy] in 2 Gy fractions administered 5 days per week for 6 weeks). Participants then received 14 additional cycles of pembrolizumab 200 mg administered Q3W. 1 cycle=21 days.

Reporting group title	Pembrolizumab + cCRT + Pemetrexed + Cisplatin
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Reporting group description:

Participants received 3 cycles of cisplatin 75 mg/m² with pemetrexed 500 mg/m² and pembrolizumab 200 mg on Day 1 of each cycle. Treatment was given in conjunction with standard TRT (60 Gy in 2 Gy fractions administered 5 days per week for 6 weeks) in cycles 2 and 3. Participants then received 14 additional cycles of pembrolizumab 200 mg administered Q3W. 1 cycle=21 days.

Reporting group values	Pembrolizumab + cCRT + Paclitaxel + Carboplatin	Pembrolizumab + cCRT + Pemetrexed + Cisplatin	Total
Number of subjects	112	104	216
Age categorical Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	49	55	104
From 65-84 years	60	49	109
85 years and over	3	0	3
Age Continuous Units: Years			
arithmetic mean	65.7	63.2	
standard deviation	± 9.1	± 9.4	-
Sex: Female, Male Units: Participants			
Female	36	40	76
Male	76	64	140
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	1	0	1
Asian	14	11	25
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	4	5
White	89	75	164
More than one race	0	0	0

Unknown or Not Reported	7	14	21
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	2	3	5
Not Hispanic or Latino	101	84	185
Unknown or Not Reported	9	17	26

End points

End points reporting groups

Reporting group title	Pembrolizumab + cCRT + Paclitaxel + Carboplatin
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Reporting group description:

Participants received 1 cycle of carboplatin area under the curve (AUC) 6 mg/mL/min with paclitaxel 200 mg/m² and pembrolizumab 200 mg on Day 1. Approximately 3 weeks later, participants received carboplatin AUC 2 mg/mL/min with paclitaxel 45 mg/m² administered weekly for 6 weeks along with 2 cycles of pembrolizumab 200 mg administered every 3 weeks (Q3W) in conjunction with standard thoracic radiotherapy (TRT) (60 Gray [Gy] in 2 Gy fractions administered 5 days per week for 6 weeks). Participants then received 14 additional cycles of pembrolizumab 200 mg administered Q3W. 1 cycle=21 days.

Reporting group title	Pembrolizumab + cCRT + Pemetrexed + Cisplatin
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Reporting group description:

Participants received 3 cycles of cisplatin 75 mg/m² with pemetrexed 500 mg/m² and pembrolizumab 200 mg on Day 1 of each cycle. Treatment was given in conjunction with standard TRT (60 Gy in 2 Gy fractions administered 5 days per week for 6 weeks) in cycles 2 and 3. Participants then received 14 additional cycles of pembrolizumab 200 mg administered Q3W. 1 cycle=21 days.

Primary: Percentage of Participants Who Developed Grade 3 or Higher Pneumonitis

End point title	Percentage of Participants Who Developed Grade 3 or Higher Pneumonitis ^[1]
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End point description:

Pneumonitis included the MedDRA preferred terms for radiation pneumonitis are acute interstitial pneumonitis, autoimmune lung disease, interstitial lung disease, pneumonitis, idiopathic pneumonia syndrome, organizing pneumonia, and immune-mediated pneumonitis. As per common terminology criteria for Adverse Events, version 4.0, pneumonitis was graded as follows: Grade (Gr) 1- asymptomatic, clinical or diagnostic observations only; intervention not indicated; Gr 2- symptomatic, medical intervention indicated, limiting instrumental activities of daily living (ADL); Gr 3- severe symptoms; limiting self-care activities of daily living (ADL), oxygen indicated; Gr 4- life-threatening respiratory compromise; urgent intervention indicated (e.g., tracheotomy or intubation); Gr 5- death. The analysis population consisted of all participants who received at least one dose of study drug.

End point type	Primary
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End point timeframe:

Up to approximately 3 years

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses were planned for this outcome measure.

End point values	Pembrolizumab + cCRT + Paclitaxel + Carboplatin	Pembrolizumab + cCRT + Pemetrexed + Cisplatin		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	112	102		
Units: Percentage of Participants				
number (confidence interval 90%)	8.0 (4.3 to 13.6)	6.9 (3.3 to 12.5)		

Statistical analyses

No statistical analyses for this end point

Primary: Overall Response Rate (ORR) Per Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST 1.1)

End point title Overall Response Rate (ORR) Per Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST 1.1)^[2]

End point description:

ORR was defined as the percentage of participants who experienced a complete response (CR; disappearance of all target lesions) or a partial response (PR; at least a 30% decrease in the sum of diameters of target lesions) and was assessed using modified RECIST 1.1 by blinded independent central review (BICR). The analysis population consisted of all participants who received at least 1 dose of study treatment.

End point type Primary

End point timeframe:

Up to approximately 3 years

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses were planned for this outcome measure.

End point values	Pembrolizumab + cCRT + Paclitaxel + Carboplatin	Pembrolizumab + cCRT + Pemetrexed + Cisplatin		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	112	102		
Units: Percentage of Participants				
number (confidence interval 95%)	71.4 (62.1 to 79.6)	75.5 (66.0 to 83.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival (PFS) Per Response Criteria in Solid Tumors Version 1.1 (RECIST 1.1)

End point title Progression Free Survival (PFS) Per Response Criteria in Solid Tumors Version 1.1 (RECIST 1.1)

End point description:

PFS was defined as the time from the first dose of study treatment to the date of the first documentation of disease progression, as determined by BICR per RECIST 1.1 or death due to any cause (whichever occurred first). Disease progression was defined as at least 20 percent (%) increase (including an absolute increase of at least 5 millimeters [mm]) in the sum of diameter of target lesions, taking as reference the smallest sum, and/or unequivocal progression of existing non-target lesions, and/or appearance of 1 or more new lesions. PFS was estimated and analyzed using the product-limit (Kaplan-Meier) method for censored data. 9999 indicates upper limit not reached at time of data cut-off due to insufficient number of participants with an event. The analysis population consisted of all participants who received at least 1 dose of study treatment.

End point type Secondary

End point timeframe:

Up to approximately 5 1/2 years

End point values	Pembrolizumab + cCRT + Paclitaxel + Carboplatin	Pembrolizumab + cCRT + Pemetrexed + Cisplatin		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	112	102		
Units: Months				
median (confidence interval 95%)	29.0 (16.6 to 48.5)	45.3 (17.9 to 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)
End point description:	
OS is defined as the time from enrollment to death due to any cause. OS was estimated and analyzed using the product-limit (Kaplan-Meier) method for censored data. 9999 indicates upper limit not reached at time of data cut-off due to insufficient number of participants with an event. The analysis population consisted of all participants who received at least 1 dose of study treatment.	
End point type	Secondary
End point timeframe:	
Up to approximately 5 1/2 years	

End point values	Pembrolizumab + cCRT + Paclitaxel + Carboplatin	Pembrolizumab + cCRT + Pemetrexed + Cisplatin		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	112	102		
Units: Months				
median (confidence interval 95%)	35.6 (26.1 to 44.2)	56.7 (41.1 to 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Who Experienced an Adverse Event (AE)

End point title	Number of Participants Who Experienced an Adverse Event (AE)
End point description:	
An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a study intervention. The number of participants with at least one AE was assessed. The analysis population consisted of all participants who received at least one dose of study drug.	

End point type	Secondary
End point timeframe:	
Up to approximately 1 1/2 years	

End point values	Pembrolizumab + cCRT + Paclitaxel + Carboplatin	Pembrolizumab + cCRT + Pemetrexed + Cisplatin		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	112	102		
Units: Participants	108	101		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Who Discontinued From Study Treatment Due to an AE

End point title	Number of Participants Who Discontinued From Study Treatment Due to an AE
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End point description:

An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a study intervention. The number of participants who discontinued treatment due to an AE was assessed. The analysis population consisted of all participants who received at least one dose of study drug.

End point type	Secondary
End point timeframe:	
Up to approximately 1 year	

End point values	Pembrolizumab + cCRT + Paclitaxel + Carboplatin	Pembrolizumab + cCRT + Pemetrexed + Cisplatin		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	112	102		
Units: Participants	48	26		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

For adverse events: Up to ~ 1 1/2 years.

All-cause mortality (ACM): Up to ~ 5 1/2 years

Adverse event reporting additional description:

All-cause mortality includes all enrolled participants. AEs include participants who received ≥ 1 dose of study treatment.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	26.1
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Reporting groups

Reporting group title	Pembrolizumab + cCRT + Pemetrexed + Cisplatin
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Reporting group description:

Participants received 3 cycles of cisplatin 75 mg/m² with pemetrexed 500 mg/m² and pembrolizumab 200 mg on Day 1 of each cycle. Treatment was given in conjunction with standard TRT (60 Gy in 2 Gy fractions administered 5 days per week for 6 weeks) in cycles 2 and 3. Participants then received 14 additional cycles of pembrolizumab 200 mg administered Q3W. 1 cycle=21 days.

Reporting group title	Pembrolizumab + cCRT + Paclitaxel + Carboplatin
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Reporting group description:

Participants received 1 cycle of carboplatin area under the curve (AUC) 6 mg/mL/min with paclitaxel 200 mg/m² and pembrolizumab 200 mg on Day 1. Approximately 3 weeks later, participants received carboplatin AUC 2 mg/mL/min with paclitaxel 45 mg/m² administered weekly for 6 weeks along with 2 cycles of pembrolizumab 200 mg administered every 3 weeks (Q3W) in conjunction with standard thoracic radiotherapy (TRT) (60 Gray [Gy] in 2 Gy fractions administered 5 days per week for 6 weeks). Participants then received 14 additional cycles of pembrolizumab 200 mg administered Q3W. 1 cycle=21 days.

Serious adverse events	Pembrolizumab + cCRT + Pemetrexed + Cisplatin	Pembrolizumab + cCRT + Paclitaxel + Carboplatin	
Total subjects affected by serious adverse events			
subjects affected / exposed	46 / 102 (45.10%)	66 / 112 (58.93%)	
number of deaths (all causes)	49	72	
number of deaths resulting from adverse events	7	12	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Non-Hodgkin's lymphoma			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Thrombophlebitis			

subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism			
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial occlusive disease			
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 102 (1.96%)	2 / 112 (1.79%)	
occurrences causally related to treatment / all	1 / 2	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Device related thrombosis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden death			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pyrexia			

subjects affected / exposed	7 / 102 (6.86%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	5 / 9	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	0 / 102 (0.00%)	2 / 112 (1.79%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 102 (0.00%)	2 / 112 (1.79%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug hypersensitivity			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pneumonitis			
subjects affected / exposed	5 / 102 (4.90%)	7 / 112 (6.25%)	
occurrences causally related to treatment / all	5 / 5	7 / 7	
deaths causally related to treatment / all	0 / 0	4 / 4	
Pleural effusion			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 102 (0.98%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Atelectasis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	2 / 102 (1.96%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pulmonary haemorrhage			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary embolism			
subjects affected / exposed	4 / 102 (3.92%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	1 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	1 / 102 (0.98%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Neutrophil count decreased			
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Platelet count decreased			
subjects affected / exposed	1 / 102 (0.98%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Radiation oesophagitis			
subjects affected / exposed	0 / 102 (0.00%)	3 / 112 (2.68%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	

Radiation pneumonitis			
subjects affected / exposed	1 / 102 (0.98%)	3 / 112 (2.68%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Tracheo-oesophageal fistula			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Supraventricular tachycardia			
subjects affected / exposed	0 / 102 (0.00%)	2 / 112 (1.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cardiac failure acute			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Myocardial ischaemia			
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocarditis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	1 / 102 (0.98%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive encephalopathy			
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metabolic encephalopathy			

subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	1 / 102 (0.98%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematotoxicity			
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	0 / 102 (0.00%)	5 / 112 (4.46%)	
occurrences causally related to treatment / all	0 / 0	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			
subjects affected / exposed	3 / 102 (2.94%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	2 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			

subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Dysphagia			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	0 / 102 (0.00%)	2 / 112 (1.79%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis			
subjects affected / exposed	0 / 102 (0.00%)	2 / 112 (1.79%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal perforation			
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Odynophagia			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			

subjects affected / exposed	1 / 102 (0.98%)	2 / 112 (1.79%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired gastric emptying			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastritis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stomatitis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	1 / 102 (0.98%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Hepatitis acute			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug-induced liver injury			

subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disease			
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Rash maculo-papular			
subjects affected / exposed	0 / 102 (0.00%)	2 / 112 (1.79%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic epidermal necrolysis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Prerenal failure			
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute kidney injury			
subjects affected / exposed	2 / 102 (1.96%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	2 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			

Hypothyroidism			
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypophysitis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Hypertrophic osteoarthropathy			
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Anal abscess			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary tract infection			
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	1 / 102 (0.98%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis bacterial			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

COVID-19			
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
COVID-19 pneumonia			
subjects affected / exposed	2 / 102 (1.96%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Catheter site infection			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	1 / 102 (0.98%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infectious pleural effusion			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective exacerbation of chronic obstructive airways disease			

subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection		
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neutropenic sepsis		
subjects affected / exposed	0 / 102 (0.00%)	2 / 112 (1.79%)
occurrences causally related to treatment / all	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Orchitis		
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia pneumococcal		
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia		
subjects affected / exposed	9 / 102 (8.82%)	14 / 112 (12.50%)
occurrences causally related to treatment / all	2 / 11	2 / 15
deaths causally related to treatment / all	0 / 2	0 / 2
Pneumocystis jirovecii pneumonia		
subjects affected / exposed	2 / 102 (1.96%)	0 / 112 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis		
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection		

subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 102 (0.00%)	4 / 112 (3.57%)	
occurrences causally related to treatment / all	0 / 0	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia necrotising			
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	2 / 102 (1.96%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	2 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrolyte imbalance			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Failure to thrive			
subjects affected / exposed	0 / 102 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			

subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypophagia		
subjects affected / exposed	1 / 102 (0.98%)	0 / 112 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Pembrolizumab + cCRT + Pemetrexed + Cisplatin	Pembrolizumab + cCRT + Paclitaxel + Carboplatin	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	100 / 102 (98.04%)	106 / 112 (94.64%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	5 / 102 (4.90%)	6 / 112 (5.36%)	
occurrences (all)	7	6	
Hypotension			
subjects affected / exposed	6 / 102 (5.88%)	11 / 112 (9.82%)	
occurrences (all)	7	11	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	41 / 102 (40.20%)	20 / 112 (17.86%)	
occurrences (all)	60	26	
Chest pain			
subjects affected / exposed	10 / 102 (9.80%)	7 / 112 (6.25%)	
occurrences (all)	12	7	
Chills			
subjects affected / exposed	3 / 102 (2.94%)	6 / 112 (5.36%)	
occurrences (all)	3	6	
Fatigue			
subjects affected / exposed	33 / 102 (32.35%)	39 / 112 (34.82%)	
occurrences (all)	38	49	
Mucosal inflammation			

subjects affected / exposed occurrences (all)	10 / 102 (9.80%) 10	6 / 112 (5.36%) 6	
Pyrexia subjects affected / exposed occurrences (all)	13 / 102 (12.75%) 14	22 / 112 (19.64%) 30	
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	29 / 102 (28.43%) 37	31 / 112 (27.68%) 36	
Dyspnoea subjects affected / exposed occurrences (all)	18 / 102 (17.65%) 19	24 / 112 (21.43%) 28	
Oropharyngeal pain subjects affected / exposed occurrences (all)	8 / 102 (7.84%) 8	2 / 112 (1.79%) 2	
Pleural effusion subjects affected / exposed occurrences (all)	2 / 102 (1.96%) 2	8 / 112 (7.14%) 8	
Pneumonitis subjects affected / exposed occurrences (all)	17 / 102 (16.67%) 19	16 / 112 (14.29%) 19	
Productive cough subjects affected / exposed occurrences (all)	9 / 102 (8.82%) 9	8 / 112 (7.14%) 8	
Psychiatric disorders			
Insomnia subjects affected / exposed occurrences (all)	7 / 102 (6.86%) 8	18 / 112 (16.07%) 21	
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	8 / 102 (7.84%) 9	8 / 112 (7.14%) 9	
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	4 / 102 (3.92%) 6	8 / 112 (7.14%) 8	
Blood creatinine increased			

subjects affected / exposed occurrences (all)	13 / 102 (12.75%) 17	6 / 112 (5.36%) 7	
Blood urea increased subjects affected / exposed occurrences (all)	7 / 102 (6.86%) 9	3 / 112 (2.68%) 3	
Lymphocyte count decreased subjects affected / exposed occurrences (all)	8 / 102 (7.84%) 12	11 / 112 (9.82%) 16	
Neutrophil count decreased subjects affected / exposed occurrences (all)	13 / 102 (12.75%) 15	19 / 112 (16.96%) 23	
Platelet count decreased subjects affected / exposed occurrences (all)	9 / 102 (8.82%) 15	16 / 112 (14.29%) 18	
Weight decreased subjects affected / exposed occurrences (all)	14 / 102 (13.73%) 14	16 / 112 (14.29%) 16	
White blood cell count decreased subjects affected / exposed occurrences (all)	11 / 102 (10.78%) 19	11 / 112 (9.82%) 17	
Injury, poisoning and procedural complications			
Radiation oesophagitis subjects affected / exposed occurrences (all)	14 / 102 (13.73%) 15	13 / 112 (11.61%) 13	
Radiation pneumonitis subjects affected / exposed occurrences (all)	12 / 102 (11.76%) 12	18 / 112 (16.07%) 18	
Radiation skin injury subjects affected / exposed occurrences (all)	8 / 102 (7.84%) 8	5 / 112 (4.46%) 5	
Cardiac disorders			
Tachycardia subjects affected / exposed occurrences (all)	3 / 102 (2.94%) 3	8 / 112 (7.14%) 9	
Nervous system disorders			

Dizziness			
subjects affected / exposed	9 / 102 (8.82%)	9 / 112 (8.04%)	
occurrences (all)	11	11	
Dysgeusia			
subjects affected / exposed	8 / 102 (7.84%)	10 / 112 (8.93%)	
occurrences (all)	8	11	
Headache			
subjects affected / exposed	13 / 102 (12.75%)	9 / 112 (8.04%)	
occurrences (all)	18	9	
Neuropathy peripheral			
subjects affected / exposed	5 / 102 (4.90%)	15 / 112 (13.39%)	
occurrences (all)	5	15	
Paraesthesia			
subjects affected / exposed	4 / 102 (3.92%)	6 / 112 (5.36%)	
occurrences (all)	4	7	
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 102 (0.98%)	12 / 112 (10.71%)	
occurrences (all)	1	13	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	33 / 102 (32.35%)	44 / 112 (39.29%)	
occurrences (all)	40	53	
Lymphopenia			
subjects affected / exposed	12 / 102 (11.76%)	11 / 112 (9.82%)	
occurrences (all)	16	13	
Neutropenia			
subjects affected / exposed	23 / 102 (22.55%)	32 / 112 (28.57%)	
occurrences (all)	29	50	
Thrombocytopenia			
subjects affected / exposed	3 / 102 (2.94%)	17 / 112 (15.18%)	
occurrences (all)	3	22	
Leukopenia			
subjects affected / exposed	8 / 102 (7.84%)	15 / 112 (13.39%)	
occurrences (all)	11	29	
Ear and labyrinth disorders			

Tinnitus			
subjects affected / exposed	11 / 102 (10.78%)	1 / 112 (0.89%)	
occurrences (all)	13	1	
Vertigo			
subjects affected / exposed	3 / 102 (2.94%)	6 / 112 (5.36%)	
occurrences (all)	3	6	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	6 / 102 (5.88%)	8 / 112 (7.14%)	
occurrences (all)	7	8	
Abdominal pain upper			
subjects affected / exposed	7 / 102 (6.86%)	3 / 112 (2.68%)	
occurrences (all)	7	4	
Constipation			
subjects affected / exposed	27 / 102 (26.47%)	24 / 112 (21.43%)	
occurrences (all)	32	28	
Diarrhoea			
subjects affected / exposed	22 / 102 (21.57%)	27 / 112 (24.11%)	
occurrences (all)	27	37	
Dyspepsia			
subjects affected / exposed	7 / 102 (6.86%)	15 / 112 (13.39%)	
occurrences (all)	9	17	
Dysphagia			
subjects affected / exposed	16 / 102 (15.69%)	27 / 112 (24.11%)	
occurrences (all)	16	31	
Gastrooesophageal reflux disease			
subjects affected / exposed	6 / 102 (5.88%)	5 / 112 (4.46%)	
occurrences (all)	6	5	
Nausea			
subjects affected / exposed	53 / 102 (51.96%)	28 / 112 (25.00%)	
occurrences (all)	77	36	
Odynophagia			
subjects affected / exposed	5 / 102 (4.90%)	11 / 112 (9.82%)	
occurrences (all)	5	14	
Oesophagitis			

subjects affected / exposed occurrences (all)	24 / 102 (23.53%) 25	17 / 112 (15.18%) 20	
Stomatitis subjects affected / exposed occurrences (all)	6 / 102 (5.88%) 7	7 / 112 (6.25%) 8	
Vomiting subjects affected / exposed occurrences (all)	20 / 102 (19.61%) 23	10 / 112 (8.93%) 11	
Skin and subcutaneous tissue disorders			
Rash maculo-papular subjects affected / exposed occurrences (all)	2 / 102 (1.96%) 2	6 / 112 (5.36%) 6	
Alopecia subjects affected / exposed occurrences (all)	6 / 102 (5.88%) 6	35 / 112 (31.25%) 35	
Pruritus subjects affected / exposed occurrences (all)	16 / 102 (15.69%) 18	15 / 112 (13.39%) 19	
Rash subjects affected / exposed occurrences (all)	14 / 102 (13.73%) 16	22 / 112 (19.64%) 27	
Endocrine disorders			
Hyperthyroidism subjects affected / exposed occurrences (all)	8 / 102 (7.84%) 9	9 / 112 (8.04%) 9	
Hypothyroidism subjects affected / exposed occurrences (all)	15 / 102 (14.71%) 16	18 / 112 (16.07%) 19	
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	11 / 102 (10.78%) 13	17 / 112 (15.18%) 22	
Back pain subjects affected / exposed occurrences (all)	5 / 102 (4.90%) 7	6 / 112 (5.36%) 8	
Musculoskeletal chest pain			

subjects affected / exposed occurrences (all)	3 / 102 (2.94%) 3	6 / 112 (5.36%) 8	
Myalgia subjects affected / exposed occurrences (all)	8 / 102 (7.84%) 9	11 / 112 (9.82%) 14	
Infections and infestations			
Pneumonia subjects affected / exposed occurrences (all)	5 / 102 (4.90%) 5	12 / 112 (10.71%) 14	
Upper respiratory tract infection subjects affected / exposed occurrences (all)	5 / 102 (4.90%) 5	8 / 112 (7.14%) 9	
Urinary tract infection subjects affected / exposed occurrences (all)	2 / 102 (1.96%) 2	7 / 112 (6.25%) 8	
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	30 / 102 (29.41%) 34	24 / 112 (21.43%) 29	
Dehydration subjects affected / exposed occurrences (all)	6 / 102 (5.88%) 7	5 / 112 (4.46%) 6	
Hyperglycaemia subjects affected / exposed occurrences (all)	6 / 102 (5.88%) 11	9 / 112 (8.04%) 13	
Hypoalbuminaemia subjects affected / exposed occurrences (all)	2 / 102 (1.96%) 2	6 / 112 (5.36%) 8	
Hypokalaemia subjects affected / exposed occurrences (all)	6 / 102 (5.88%) 8	9 / 112 (8.04%) 10	
Hyponatraemia subjects affected / exposed occurrences (all)	3 / 102 (2.94%) 5	10 / 112 (8.93%) 15	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported